



Hospital Products Division

Abbott Laboratories  
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200 Abbott Park Road  
Abbott Park, Illinois 60064-3537

2006 JUN 29 12:50

June 27, 2000

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Dear Sir or Madam:

**Re: Citizen Petition 00P-0787/CP 1 (dated February 16, 2000)  
Amendment – Request for Variance**

Abbott Laboratories herein submits four copies of this Petition Amendment under 21 CFR Part 898.14 to request a 120-day variance from compliance with the effective date of the 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables (hereafter "Performance Standard").

It is the understanding of Abbott Laboratories that a variance is not effective until the Agency approves the request under 21 CFR 10.30(e)(2)(i).

**I. History**

The above-referenced Citizen Petition relates to the Abbott Laboratories catheter-introduced RV Pacing Lead, List No. 50345, which is a Transluminal Pacing Lead indicated for temporary ventricular pacing only. This device is classified as Class II, under 21 CFR 870.3680, and was cleared under 510(k) 962467 on September 17, 1996.

The Citizen Petition requested exemption from the Performance Standard of 21 CFR Part 898, Performance Standard for Electrode Lead Wires and Patient Cables, and was submitted to the Agency on February 16, 2000. That request was based on a variety of factors that included but were not limited to:

1. The electrode connectors are covered with a plastic sheath that must be removed prior to use.
2. The individual connectors are labeled "WARNING do not plug the male pin connectors into a wall socket. Such use can result in serious injury or death to the patient or operator."
3. The pacing lead cannot reach a mains outlet since it is less than 8 inches long from the catheter adapter to the electrode connector.
4. Most of the cables provided by manufacturers that are used with the Abbott RV Pacing Lead have already been modified to meet IEC-601-1 subclause 56.3(c).

00P-0787

CP2



June 27, 2000  
Food and Drug Administration  
Dockets Management Branch  
Page 2

Although the Agency acknowledged that these points supported the exemption request, FDA denied Abbott's petition for exemption on April 18, 2000. A copy of this denial letter is appended as Exhibit I. Abbott is currently working towards meeting the Performance Standard by converting the exposed ends of our pacing leads (Exhibit II), as suggested in the Agency's Safety Letter entitled, "*FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used with Medical Devices*," issued December 28, 1993. A copy of this letter is appended in Exhibit III. Although this effort to meet the Performance Standard is in progress, the process of conversion to sheath-tipped protected leads will take approximately four (4) additional months (120 days).

## **II. Use of the Abbott RV Pacing Lead**

The Abbott pulmonary artery pacing catheter represents a significant portion of the total domestic market for pulmonary artery (right heart) catheters. These catheters are inserted by an invasive procedure in critically ill or unstable patients in operating rooms and intensive care units. They are used both diagnostically and therapeutically to carefully guide the ongoing care of these high-risk patients. The following is a partial listing of life threatening conditions, which may call for monitoring with a pulmonary artery catheter:

- Acute myocardial infarction
- Acute left ventricular failure
- Cardiac surgery
- Septic shock or other life-threatening infection
- Cardiac tamponade
- Pulmonary embolism
- Acute respiratory failure
- Complicated pregnancy

In many of the conditions listed above, abnormalities of the patient's cardiac conduction system often require emergency cardiac pacing.

Abbott Laboratories is one of the largest suppliers of pulmonary artery pacing catheters. Without the availability of an Abbott pacing lead, a significant clinical need for the ability to provide emergency cardiac pacing will not be served. The Abbott Critical Care Products Pacing Lead is intended for use only with an Abbott Pulmonary Artery Catheter with RV Paceport. The cross-section and size of the pacing lumen on the pacing catheter have been designed specifically to accommodate the Abbott Pacing Lead. Since there are currently no alternative pacing leads that are recommended for use with the Abbott Pacing Catheter, patients in need of cardiac pacing would be subjected to another invasive procedure with its attendant morbidity and mortality.



June 27, 2000  
Food and Drug Administration  
Dockets Management Branch  
Page 3

**III. Reason for Variance from Performance Standard Effective Date**

Four months is a critical amount of time for this device to be unavailable for patients and clinicians, and there is only one other manufacturer of this type of pacing lead catheter equipment. Therefore, this variance is being requested to keep this critical care medical device available to patients and clinicians while our Abbott manufacturing facility in Salt Lake City works to qualify, test and implement the changes necessary for the RV Pacing Lead to be in compliance with the Performance Standard.

**IV. Scope of Variance**

Abbott is seeking a variance for compliance with 21 CFR Part 898 Performance Standard for the Abbott Laboratories RV Pacing Lead List No. 50345. We seek this variance for our RV Pacing Lead which is used with the Abbott Thermodilution Catheter List Nos. 41252 and 41300, as well as the Abbott Opticath® Pacing Catheter List No. 50344.

**V. Environmental Impact**

The Citizen Petition, as an exemption from standard, is exempt under 21 CFR 25.24(e)(3). Therefore, no environmental impact statement is required.

**VI. Certification**

I, the undersigned, hereby certify that, in my capacity as Manager, Regulatory Affairs, for Abbott Laboratories, Hospital Products Division, to the best of my knowledge, this Petition Amendment includes all information and views on which the Petitioner relies, and includes representative data and information known to the Petitioner which are unfavorable to the Petition Amendment.

I trust you will find this request for variance satisfactory. Should you require additional information, please contact me at the numbers listed below. Thank you for your continued interest in our Citizen Petition.

Sincerely,  
ABBOTT LABORATORIES

Thomas P. Sampogna  
Manager, Regulatory Affairs  
Hospital Products Division  
Phone: (847) 935-3715  
Fax: (847) 938-7867  
e-mail: [sampotp@HPD.abbott.com](mailto:sampotp@HPD.abbott.com)

## Table of Contents

		Page
Exhibit I	FDA correspondence dated April 18, 2000	1
Exhibit II	Proposed Abbott Pacing Lead wire tip conversion	4
Exhibit III	FDA Safety Letter issued December 1993	6

**Exhibit I**  
**FDA correspondence dated April 18, 2000**



DEPARTMENT OF HEALTH & HUMAN SERVICES

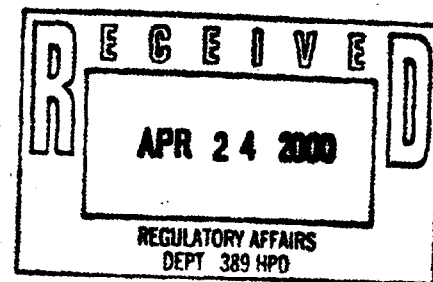
Public Health Service

DEF-TS-255

Food and Drug Administration  
Rockville MD 20857

APR 18 2000

Mr. Thomas P. Sampogna  
Manager, Regulatory Affairs  
Hospital Products Division  
Abbott Laboratories  
D-389, Bldg. AP30  
200 Abbott Park Road  
Abbott Park, Illinois 60064-3537



Ref: 00P-0787/CP 1

Dear Mr. Sampognai:

This is in response to your Citizen Petition dated February 16, 2000, in which you request an exemption from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, Part 898 of Title 21 of the Code of Federal Regulations. Your request covers a device identified as the RV Pacing Lead, List No. 50345-03.

Your petition is requesting an exemption from the performance standard because the RV Pacing Lead is less than eight (8) inches long from the catheter attachment to the electrode lead connector. When attached to the patient, the lead wire cannot physically reach a mains outlet. After considering all the points raised by your petition, I am denying your request for the reasons explained below.

Your petition provides numerous arguments in support of your request. It states that: temporary pacing leads are used in distinct areas of a hospital such as a sterile surgical suite, intensive care, cardiac catheterization lab and emergency treatment areas; there are usually no AC access mains in a sterile area; the personnel that would use these devices are highly trained professional clinicians who will not accidentally plug a pacing lead into an electrical outlet; after the pacing lead has been introduced into the catheter, the remaining exposed segment of the lead is either inserted into an external pacemaker or into a reusable cable that is then inserted into the pacing equipment; these devices are not used outside of a hospital; the electrode connectors are covered with a plastic sheath that must be removed prior to use; the individual connectors are labeled "WARNING do not plug the male pin connectors into a wall socket. Such use can result in serious injury or death to the patient or operator;" the pacing lead can not reach a mains outlet since it is less than eight (8) inches long from the catheter adapter to the electrode connector; most of the cables provided by manufacturers that are used with the Abbott RV Pacing Lead have already been modified to meet IEC-601-1 subclause 56.3(c); temporary pacing leads have been used for many years without a reported injury due to the incorrect placement of a pin connector into an electrical outlet or electrical power cable; Medtronic Corporation has requested and received a similar exemption (docket number 98P-0330) for a device that also has an electrode connector.

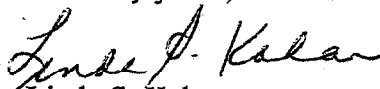
I am denying your request for an exemption for the device identified as the RV Pacing Lead based on the fact that none of the reasons given above preclude the attachment of this lead to a power cord that is attached to an electrical outlet or electrical shock caused by the exposed lead coming in contact with a bed or table.

This risk exists even though your device only extends eight (8) inches from the patient. While there may not be any electrical outlets in a sterile area, there are outlets in other areas of the hospital where this device may be used, such as intensive care or emergency treatment rooms. The argument that these devices are used by highly trained professionals in a hospital was addressed in the preamble of the performance standard. The preamble states that there have been twenty-four cases of macro shock or electrocution, including three electrocutions involving nurses. FDA acknowledges that some areas of a health care setting are more stressful than others, but human error can and does occur in all settings. A patient should not needlessly be exposed to a known and preventable risk simply because it has not happened yet in a particular area of a facility. Your argument that the ends of the electrode lead wires are covered with a sheath does not prevent your device from being plugged into a power cable or contacting a conductive surface once the sheath is removed. The preamble to the performance standard also addressed the issue concerning the use of warning labels to reduce risk. FDA has determined that the continued marketing of unprotected electrode lead wires and patient cables, no matter how they are labeled, presents an unreasonable and substantial risk of illness or injury to individuals, and provides no benefit to the public health that is not provided by protected electrode lead wires and patient cables. Patient cables used with your RV Pacing Lead have been modified to comply with the performance standard. Your device should be modified to complete the task.

The petition granted to Medtronic under docket number 98P-0330 was for a special type of temporary pacemaker electrode identified as a heart wire that includes a breakaway needle intended to pierce the chest wall. That exemption was granted based on a clinical argument that the risk of adverse medical consequences from using heart wires that comply with the performance standard outweighs the risk of electrical shock to the patient. However, no clinical argument is provided in your petition to show why your device cannot be designed to meet the performance standard and still accomplish its clinical purpose.

I trust that this is responsive to your request. If additional information is required, please contact Kent Berthold in our Office of Compliance at (301) 594-4648.

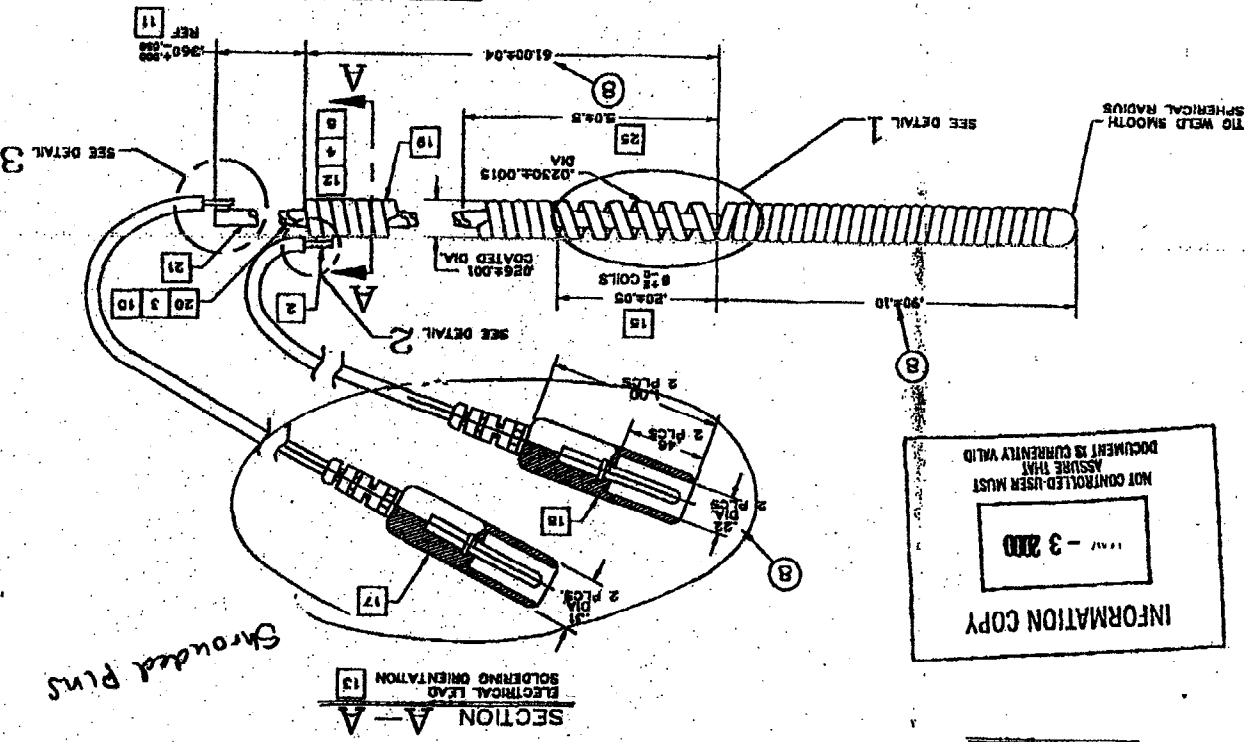
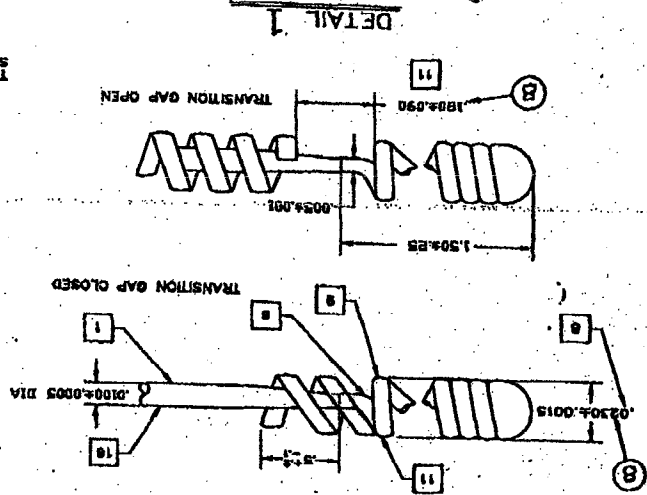
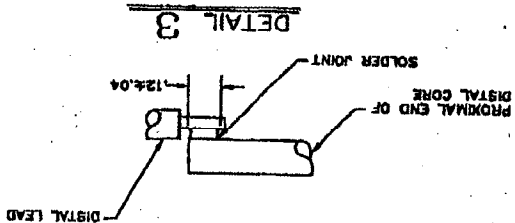
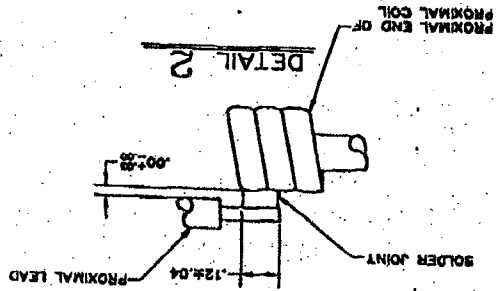
Sincerely yours,

  
Linda S. Kahan

Deputy Director for Regulations  
and Policy  
Center for Devices and  
Radiological Health

**Exhibit II**  
**Proposed Abbott Pacing Lead wire tip conversion**

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[illegible]

**Exhibit III**  
**FDA Safety Letter issued December 1993**



**FDA Public Health Advisory:  
Unsafe Electrode Lead Wires and Patient Cables Used With Medical Devices**

December 28, 1993

To: Directors of Nursing, Risk Managers, Biomedical/Clinical Engineering Departments

On September 3, 1993, FDA issued a Safety Alert warning health care professionals of the potential hazards of using unsafe electrode lead wires and patient cables with apnea monitors. **I am now extending that warning to include all other devices that may use electrode lead wires with unprotected pins.** Examples of some of these devices include, but are not limited to:

cardiac monitors,  
electrocardiographs (ECGs),  
electroencephalographs (EEGs),  
electromyographs (EMGs),  
electrophysiology equipment,  
multi-parameter patient monitors,  
muscle stimulators,  
nerve stimulators,  
neurostimulators, and  
respiratory monitors.

**The use of electrode lead wires with unprotected pins is hazardous to patients. FDA has received sporadic reports of shocks, burns and electrocutions when electrode lead wires with unprotected pins were plugged directly into a power source.**

The attached illustration may be helpful in understanding both safe and unsafe electrode lead wire and patient cable connections; we recommend that you post copies in all appropriate areas of your facility.

Although manufacturers have been changing the design of their electrode lead wires and patient cables to minimize the hazard, some health care facilities still use older models of electrode lead wires and patient cables, creating a potential hazard. If you still have these older models, we recommend that you immediately:

- Alert all staff to the hazard of using electrode lead wires with unprotected pins by distributing copies of this advisory to all units in your facility that use medical devices with patient electrode lead wires, including: Critical Care, Emergency Room, Operating Room, Medical-Surgical, Pediatric, Neonatal, and Purchasing Departments. Also distribute copies to home health care providers and suppliers affiliated with your facility.
- Replace electrode lead wires that have unprotected pins with lead wires that have protected pins if they are commercially available. Replace patient cables with those that accept only protected pins. *Note: Adapters for patient cables are available from some manufacturers.* Discard or destroy all unsafe lead wires and patient cables so they cannot be accidentally used.

Until all electrode lead wires with unprotected pins and all patient cables that accept unprotected pins are replaced or fitted with adapters, we recommend you take the following precautions:

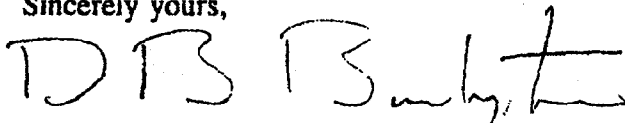
- For devices that use patient cables, disconnect patients only at the device or at the patient electrode. **DO NOT** disconnect patients from devices at the junction between the lead wire and the patient cable. Place tape over the connection between the electrode lead wire and the patient cable to make it inconvenient to disconnect the patient at this junction.
- Flag or label all detachable 120-volt power cords at the female end with a warning. This warning should alert users to the presence of hazardous voltage and/or the danger of connecting lead wires with unprotected pins into a power cord.
- Hard-wire or clamp all detachable 120-volt power cords to their respective devices so they cannot be removed by the user.

For further information on this issue, see: ECRI. Risk of electric shock from patient monitoring cables and electrode lead wires. Health Devices 1993; 22(5-8):301-303.

Please remember that the Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths, serious illnesses and injuries associated with the use of medical devices to FDA or to the manufacturer. You may report such incidents by phoning 301-427-7500, by FAXing 301-881-6670, or by writing FDA, CDRH, MDR User Reporting, P.O. Box 3002, Rockville, MD, 20847-3002.

Questions regarding this advisory may be directed by mail to the Office of Surveillance and Biometrics, FDA, HFZ-510, 1390 Piccard Drive, Rockville, MD 20850, or by FAX at 301-594-2968. Thank you for your help in this important effort.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'D. B. Burlington', with a stylized flourish at the end.

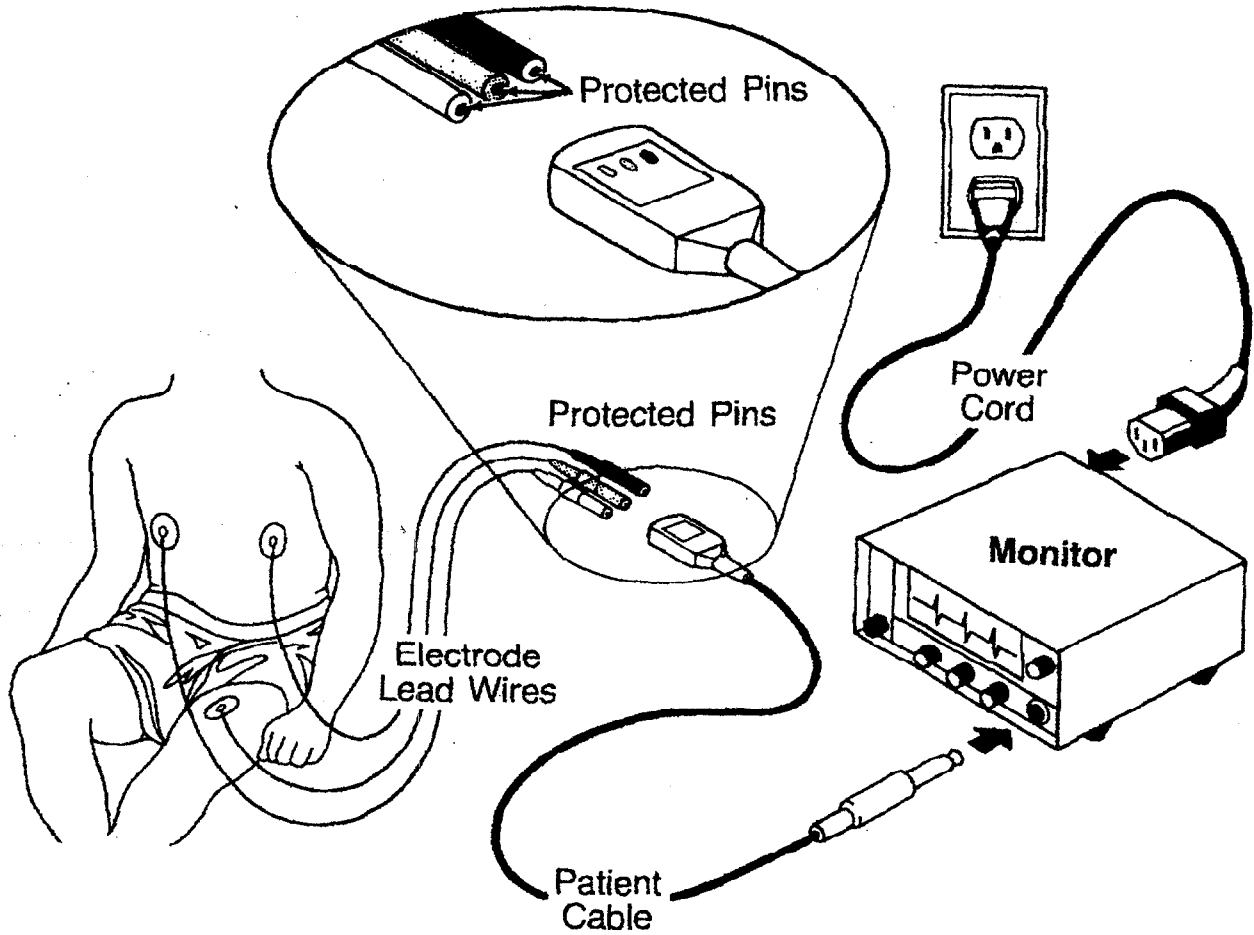
D. Bruce Burlington, M.D.

Director

Center for Devices and Radiological Health

## **SAFE**

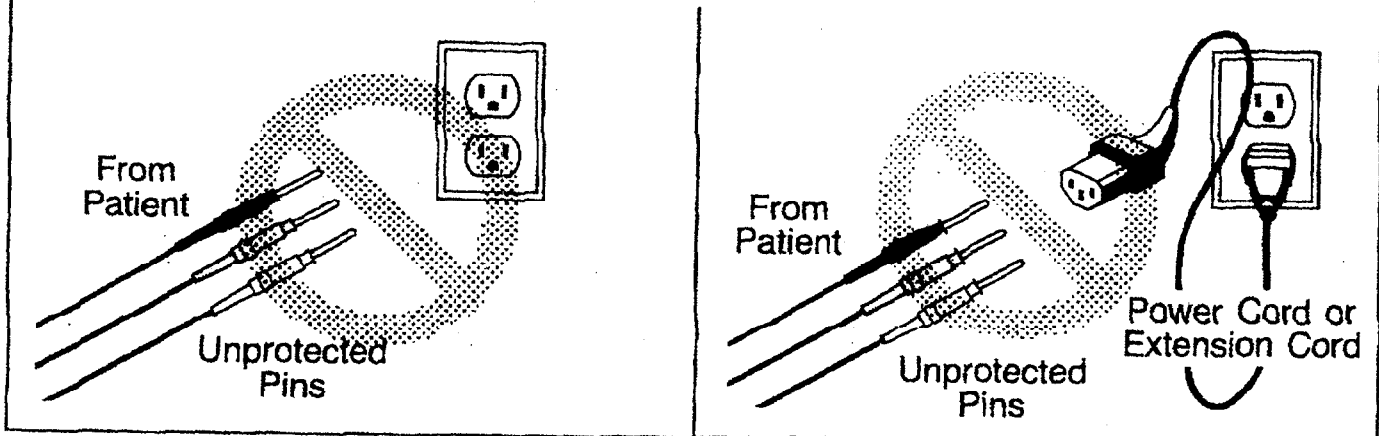
### **Lead Wires with Protected Pins and Correct Connections**



Use only lead wires that have protected pins. Protected pins can not accidentally be plugged into power cords or electrical outlets.

## **UNSAFE**

### **Lead Wires with Unprotected Pins and Incorrect Connections**



From: ANTOINETTE SLATER (847)937-6449  
ABBOTT LABORATORIES  
DEPT 0389, BLDG AP30  
100 ABBOTT PARK RD  
ABBOTT PARK, IL, 60064

SHIPPER'S FEDEX ACCOUNT #

**FedEx.**

To: Dockets Management Branch (847)937-6449  
FDA Dept of Health & Human Services  
Room 1061  
5630 Fishers Lane  
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SHIP DATE: 28JUN00  
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Ref: Cit Petition Request

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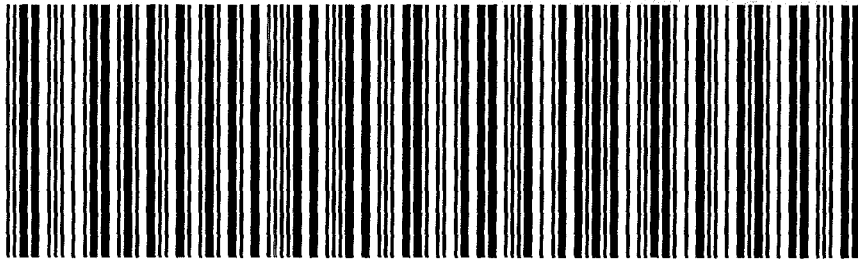
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